Office Action Summary

Application No.	Applicant(s)
10/090,215	Dubin et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 4, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-22* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-9, 14, drawn to a nucleic acid encoding the protein of SEQ ID NO:7, a vector, a host cell and a method of producing the protein, classified in Class 435, subclass 69.1.

Group II. Claims 1-9, 14, drawn to a nucleic acid encoding the protein of SEQ ID NO:9, a vector, a host cell and a method of producing the protein, classified in Class 435, subclass 69.1.

Group III. Claims 1-9, 14, drawn to a nucleic acid encoding the protein of SEQ ID NO:12, a vector, a host cell and a method of producing the protein, classified in Class 435, subclass 69.1.

Group IV. Claims 10-11, drawn to protein comprising SEQ ID NO:7, classified in Class 530, subclass 350.

Group V. Claims 10-11, drawn to protein comprising SEQ ID NO:9, classified in Class 530, subclass 350.

Group VI. Claims 10-11, drawn to protein comprising SEQ ID NO:12, classified in Class 530, subclass 350.

Group VII. Claims 12-13, drawn to an antibody to the protein set forth in SEQ ID NO:7, classified in Class 530, subclass 387.1.

Group VIII. Claims 12-13, drawn to an antibody to the protein set forth in SEQ ID NO:9, classified in Class 530, subclass 387.1.

Group IX. Claims 12-13, drawn to an antibody to the protein set forth in SEQ ID NO:12, classified in Class 530, subclass 387.1.

Group X. Claims 15-17, drawn to a method for identifying compounds that modulate human VR3 receptor protein activity, classified in Class 435, subclass 7.1.

Group XI. Claims 18-21, drawn to a compound that modulates human VR3 receptor protein activity, Class and subclass undeterminable.

Group XII. Claim 22, drawn to a method of treatment by administering a compound that modulates human VR3 receptor protein activity, Class and subclass undeterminable.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acids of Groups I-III can be used to make hybridization probes or can be used in gene therapy as well as in the production of the specific proteins of interest. The proteins of Groups IV-VI can be used other than to make the specific antibodies of Groups VII-IX, respectively, such as used as probes, or used therapeutically or diagnostically (e.g. in screening). Although the antibodies of Groups VII-IX can be used to obtain the nucleic acids of Groups I-III, respectively, they can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically. The nucleic acid of Group I, can only be used to produce the protein of Group IV while the nucleic acid of Group II can only be used to produce the protein of Group V.

Inventions I-III and IV-VI are related as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP. § 806.05(f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions IV-VI and X are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. § 806.05(h)). In the instant case the products as claimed can be used as antigen in the production of the specific antibodies.

Inventions X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of invention III can also be used in immunochromatography.

Inventions I and X, XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IV-VI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VII-IX and X, XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions X, XII, are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 27, 2003